

**REMARKS**

Claims 9-11 and 14-17 are currently pending.

**I.     The Claim Objections**

Claim 13 is objected to under 37 C.F.R. 1.75 as allegedly being a substantial duplicate of claim 11.

For the purposes of advancing prosecution, Applicants have cancelled claim 13. Therefore, the objection to claim 13 is moot.

**II.    The Rejection under 35 U.S.C. 112, First Paragraph**

Claims 9-11 and 13-17 are rejected under 35 U.S.C. 112, first paragraph, as allegedly containing failing to comply with the written description requirement.

Claim 9 is amended to clarify the procedure of the alternate soaking. A gradient of calcium phosphate can be formed by alternately soaking one side of a biodegradable polymeric material in a calcium ion-containing solution and the same side as the aforementioned one side in a phosphate ion-containing solution. That is, in the present invention, the alternate soaking is conducted by alternately soaking the same side of a biodegradable polymeric material in a calcium ion-containing solution and then a phosphate ion-containing solution as shown in Examples of page 11 (as cited by the Examiner), not by alternately soaking the opposite side in the solutions.

For the purposes of advancing prosecution, Applicants have deleted the term “part”.

For the purposes of advancing prosecution, Applicants have amended claim 17 to recite “constant gradient”.

For the above reasons, it is respectfully submitted that the subject matter of Applicants' claims is fully described in Applicants' disclosure and it is requested that the rejection under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

**III. The Rejection under 35 U.S.C. 112, Second Paragraph**

Claims 9-11 and 13-17 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite.

Again, claims 9 and 17 have been amended for clarity.

As to claim 9, the language "composition" before "gradient of calcium phosphate" has been deleted for clarity as requested by the Examiner.

Claim 15 has been amended to depend from claim 9. Applicants also respectfully traverse the Examiner's position. claim 15 is a method for producing "the composite material according to claim 9" and uses "the biodegradable polymeric material" [of claim 9]. Thus, using the polymeric material as recited in claim 9 is already present in claim 15 due to its dependency therefrom.

For the above reasons, it is respectfully submitted that Applicants' claims are clear and definite and it is requested that the rejection under 35 U.S.C. §112 be reconsidered and withdrawn.

**IV. The Art Rejections**

Claims 9-11 and 13-17 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Mattern et al. (6,969,523) or Yannas et al. (4,947,840) in view of Akashi et al. (6,387,414) and Sherwood et al. (6,454,811), and if necessary in further view of Taguchi et al.

(Biomaterials).

Claims 9, 15, 16, and 17 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Akashi et al.

Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Akashi et al. in view of Mattern et al. or Yannas et al.

The Examiner asserts that it would have been obvious to provide hydroxyapatite in the cross-linked collagen/glycosaminoglycan scaffold of Mattern et al. and Yannas et al. by alternately soaking the scaffold in a calcium ion-containing solution and then a phosphate ion-containing solution as suggested by Akashi et al. to provide a composite for use as artificial tissue.

Applicants respectfully traverse the Examiner' assertions in the rejections and respectfully submit that the present invention would not have been obvious from Akashi et al alone, Mattern and Yannas in view of Akashi and Sherwood with or without Taguchi, or Akashi in view of Mattern and Yannas, as explained in further detail below.

Firstly, a gradient of calcium phosphate cannot be formed by alternate soaking method of Akashi et al. As described above, a gradient of calcium phosphate can be formed by alternately soaking only one side of a biodegradable polymeric material in a calcium ion-containing solution and then a phosphate ion-containing solution. In the method of Akashi et al., a gradient of calcium phosphate cannot be formed, since the whole (entire) of the matrix is alternately soaked in a calcium ion-containing solution and then a phosphate ion-containing solution.

Secondly, Mattern et al. and Yannas et al. disclose a matrix consisting of a cross-linked

collagen and glycosaminoglycan. However, Mattern et al. and Yannas et al. do not have any description about a gradient of calcium phosphate in the matrix. And they do not teach or suggest any method to achieve the gradient of calcium phosphate in the matrix and any effect thereof. As described above, Akashi et al. also does not disclose a method for forming a gradient of calcium phosphate as in the present invention. Therefore, even if disclosures of Akashi et al. and those of Mattern et al. or Yannas et al. are combined, the constitution and effect of the present invention cannot be attained. Therefore, the present invention is not obvious from the disclosure of the cited references. The secondary references do not overcome the deficiencies in the primary references.

In addition, according to the gradient of calcium phosphate the biodegradable polymeric material of the present invention, one side has an ability to induce bone formation due to an action of calcium phosphate and the other side functions as a scaffold for soft tissue such as cartilage. Such remarkable effects are unexpected in view of the art and can be obtained by the present invention for the first time.

For the above reasons, it is respectfully submitted that the subject matter of claims 9-11 and 14-17 is neither taught by nor made obvious from the disclosures of Akashi et al alone, Mattern and Yannas in view of Akashi and Sherwood with or without Taguchi, or Akashi in view of Mattern and Yannas and it is requested that the rejections under 35 U.S.C. §103(a) be reconsidered and withdrawn.

V. **Conclusion**

In view of the above, Applicants respectfully submit that their claimed invention is allowable and ask that the objections to the claims, the rejections under 35 U.S.C. §112 and the rejections under 35 U.S.C. §103 be reconsidered and withdrawn. Applicants respectfully submit that this case is in condition for allowance and allowance is respectfully solicited.

If any points remain at issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the local exchange number listed below.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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